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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

WOO, JULIAN W

| | |
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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary

| | | |
|--------------------------------------|-------------------------------------|--|
| Application No. 09/988,541 | Applicant(s) ARCIA ET AL. | |
| Examiner Julian W. Woo | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 and 62 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10, 11, 15, 22, 23, 37, 38 and 62 is/are rejected.
- 7) ☒ Claim(s) 5-9, 12-14, 16-21, 24-36, 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 1-4, 10, 11, 15, 37, 38, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald (5,824,010). McDonald discloses the invention substantially as claimed. McDonald discloses, in, e.g., figures 11A and 11B, and in col. 6, line 62 to col. 7, line 20, a device or graft suturing device for suturing an end of a first body duct to a hole in the side of a second body duct, where the device comprises a structure for holding the end of the first body duct (via sutures attached to the first body duct and connected to needles held by the structure), a plurality of needles arranged on the structure, a cylindrical shaft (38), and a plurality of curved guide channels (at 44) defining a plurality of paths for guiding the needles and radially configured about the shaft. However, McDonald does not specifically disclose that the needles are arranged

Art Unit: 3731

to be passed into the first body duct and into the hole of the second body duct, when the end of the first body duct is on the structure adjacent to the hole in the second body duct. Nevertheless, McDonald discloses that the needles are "pointed at each end and suitably curved" to pass through a first body duct ("graft blood vessel") first and then positioned in the needle guide and the hole of a second body duct ("host blood vessel"). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to arrange the needles, so that they are passed into the first body duct and into the hole of the second body duct, when the end of the first body duct is on the structure (i.e., at least contacting the structure) and adjacent to the hole in the second body duct. Such a procedure would allow guidance of the needles and sutures between adjacent body ducts and completion of an anastomosis.

McDonald also does not disclose a kit, where the kit includes the device, instructions for the device's use and a package adapted to contain the device and the instructions. Nevertheless, it also would be obvious to one having ordinary skill in the art at the time the invention was made, to construct a kit including instructions and the device contained in a package. Such a kit would be convenient means for presenting a sterile, intact instrument for a surgeon's use and instructions for the surgeon's education in the proper use of the instrument.

3. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald in view of Amarasinghe (4,553,543). McDonald discloses the invention substantially as claimed, but does not disclose that the needles comprise shape memory alloy or a superelastic material. Amarasinghe teaches, in col. 3, lines 19-28, a

Art Unit: 3731

suturing device with flexible needles made of spring steel, a superelastic, shape memory alloy. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Amarasinghe, to form the needles of McDonald out of a shape memory alloy or a superelastic material. Such a material would allow the needles to bend easily and move through the guide channels, and the material would provide sufficient rigidity to maintain the points of the needles.

Allowable Subject Matter

4. Claims 5-9, 12-14, 16-21, 24-36, and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a device for suturing an end of a first body duct to a hole in the side of a second body duct, where the device includes, inter alia, a structure for holding the end of the first body duct and a plurality of needles arranged on guide channels of the structure, where the structure includes a shaft with a tubular surface against which the needles are positioned, where the guide channels comprise guide tubes, where the guide channels have a longitudinal slot, where the guide channels each have a gap separating first and second portions of a channel, and where the structure includes a tubular constraint or inner and outer tubes.

Response to Amendment

6. Applicant's arguments filed on September 16, 2005 have been fully considered but they are not persuasive: See the rejection above. That is, the McDonald reference does indeed disclose a plurality of needles with the needle guide (besides the single needle with the needle guide).

The rejection under 35 U.S.C. 112, 2nd paragraph has been overcome.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

November 2, 2005